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PRINCIPAL INVESTIGATOR: Dmitry Oleynikov, MD Shane Farritor, PhD

CONTRACTING ORGANIZATION: University of Nebraska Medical Center Omaha, NE 68198-7835

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14. ABSTRACT

Two robotic prototypes capable of insertion through a single incision were designed. One robot was a smaller 4 degree of freedom (DOF) robot, while the other robot was a 5 DOF robot. Both of these robots consisted of two halves that could be separately inserted through a single incision, a surrogate for a natural orifice with regard to size. Insertion was accomplished through a single abdominal wall incision, which facilitates experimental progress as we move toward natural orifice insertion. During insertion, each half of the robot contorts to allow insertion into the limited space of the non-insufflated abdominal cavity. The halves are then pulled together and rigidly connected through the use of a central insertion rod and the cavity is then insufflated. Supporting the robot in this way allows for reorientation of the robot into various abdominal quadrants during a process that takes approximately 10 seconds.

15. SUBJECT TERMS

robotic telesurgery, in vivo robot, triage in forward environment, remote first responder, laparoscopic surgery

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INTRODUCTION

The objective of this project is to create a remotely controlled image-guided, mini-robot that can be placed entirely into the peritoneal cavity through the mouth to perform abdominal surgery and to demonstrate the feasibility of this approach in a non-survivable animal surgery. At the completion of this project, our expectation is to have developed and demonstrated the effectiveness of an image-guided, in vivo miniature robot for use in transgastric abdominal surgery. This is an important step toward our long-term goal of using image-guided in vivo mini-robots to make many surgeries in the peritoneal cavity less invasive than currently possible with existing technology. The projected outcomes have the potential to lay the foundations for important advancements in MIS.

This work is the second part of a two-phase project. The first phase focused on the design and construction of an in vivo camera robot. The second phase of this project will focus on in and ex vivo experimentation, while ensuring that the system can withstand the conditions of forward, military environments.

BODY

Major components of the Natural Orifice Translumenal Endoscopic Surgery (NOTES) robot will be designed, a detailed design of the system will be created, and a prototype robot will be built.

Major components of the NOTES robot were designed through iteration of previous studies. The first major iteration was the reorientation of the body segment of the 4 degree of freedom (DOF) surgical robot. By splitting the body segment into two halves and rotating the motors 90 degrees, kinematics of the robot were improved to better perform surgical tasks and also provided a more viable insertion method. Improvements to this robot include changes to improve reliability: technical modifications to reduce slipping in the robot that ultimately improve accuracy and the addition of heat sinks to avoid motor overheating. Multiple animal surgeries were performed in porcine models with iterations of this 4 DOF robot; procedures performed included open cholecystectomies and colectomies. These surgeries were performed using grasper and cautery end effectors. Vision for the surgeon in control of the robot was provided by standard laparoscopes, lighting sources commonly available in surgical rooms, and onboard cameras and lighting sources. The onboard cameras had pan and tilt capabilities. Both monoscopic and stereoscopic onboard vision systems were utilized in surgical procedures. The robot was controlled by a surgeon using Phantom Omni (Sensable) controllers.

Using knowledge and experience gained from the 4 DOF robot, two robotic prototypes capable of insertion through a single incision were designed. One robot was a smaller 4 DOF robot, while the other robot was a 5 DOF robot. The additional degree of freedom allows for multiple "angles of attack" through additional dexterity. Both of these robots consisted of two halves that could be separately inserted through a single incision, a surrogate for a natural orifice with regard to size. Insertion was accomplished through a single abdominal wall incision, which facilitates experimental progress as we move toward natural orifice insertion (see Appendices A and B). During insertion, each half of the robot contorts to allow insertion into the limited space of the non-insufflated abdominal cavity. The halves are then pulled together and rigidly connected through the

use of a central insertion rod and the cavity is then insufflated. Supporting the robot in this way allows for reorientation of the robot into various abdominal quadrants during a process that takes approximately 10 seconds. With this approach both prototypes described above have been inserted into live porcine models through a single incision. The central insertion rod was designed to allow for a laparoscope to provide vision and lighting for the surgeon. Once inserted, these robots have successfully manipulated tissue in all four quadrants of the abdominal cavity. These robots were also controlled by Phantom Omni controllers and a kinematically matched master controller.

A kinematic analysis of the robot will be performed to establish the correct configuration to produce the required endpoint forces and speeds.

Detailed kinematic analysis of the robot has been performed. The information gained through this analysis was coupled with data recorded during surgical tests to improve the configuration of the robot. A robot prototype with a much larger workspace and smaller overall size resulted from this study; additional details can be found in the appended abstract presented at the 2010 annual meeting of the Society of Laparoendoscopic Surgeons (see Appendix C). Several calculations were also performed utilizing the Jacobian from the kinematics to ensure that the motors used would produce enough torque and speed to reach the required forces, speeds, and endpoints.

The performance of the prototype system in ex vivo experiments will be evaluated. These results will be used to optimize the design of the final system in an iterative fashion. Benchtop experiments have been repeatedly performed to test the capabilities of the 4 DOF surgical robot; end effectors forces, speeds, and positioning accuracy were tested. Methodology and results for the force and speed tests can be found in Workspace and Force Capabilities of a Miniature Multi-Functional Surgical Robot (Appendix D). Accuracy was tested through various bench top laparoscopy FLS training tasks with the robot controlled by both surgeons and non-surgeons.

Methods and apparatus will be designed for controlled delivery/removal of materials through a NOTES approach.

A set of suitable biocompatible polymers have been identified and an optimal material (silicone rubber) has been selected for use as an overtube for a NOTES-based material delivery system. With this material selected, a first generation delivery system (primary functional components only) has been designed and prototyped (Figures 1-2). The current delivery system consists of three main components (overtube, helical driver and shuttle) and will function in a manner similar to a twist-end mechanical pencil. By rotating the driving spring, the shuttle will advance through the overtube in either direction depending on the direction of rotation.

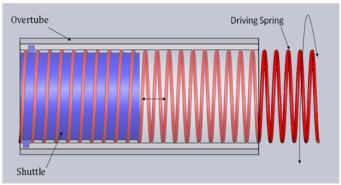


Figure 1: Cutaway drawing of the material delivery system design



Figure 2: Prototype construction showing only a portion of the overtube with helical driver

Preliminary prototype tests displayed undesirable levels of friction between the overtube and driving spring which caused the spring to advance through the overtube. Other results from testing showed a lack of strength in the peripheral features of the shuttle which lead their eventual failure. A finite element stress analysis of shuttle and its periphery in asbuilt conditions was performed to improved strength in future design revisions.

Current work aims to lessen frictional effects by changing the overtube inner geometry and surface finish, address clearances between the spring and overtube, and design an integrated compliant mechanism for securing materials in the delivery system. Furthermore, long term design requirements of additional, integrated components that improve device functionality will be addressed. These may include tip steering for overtube insertion, lighting/vision, and various modular attachment designs. Finite element analysis will be utilized extensively as a design optimization tool and to reduce iterative prototype costs.

The robot's effectiveness will be demonstrated through various NOTES procedures in porcine models.

Non-survival procedures in a porcine model were performed. A significant amount of insight was gained from these tests and several important improvements to the robotic prototypes were subsequently made (Appendices A and B). The surgical robot prototype proved to be very effective. Some of the key accomplishments were:

- Full cholecystectomy six minute completion time
- Suturing
- Gastrotomy
- Partial colon resection

• Completion of a fully closed procedure - the robot was inserted through a twoinch incision and assembled inside the body

KEY RESEARCH ACCOMPLISHMENTS

- Designed and built two end-effectors which mimic laparoscopic tool handles
- Integrated mono-polar cautery in a robotic prototype
- Improved software functionality
- Designed and built a pan and tilt camera
- Redesigned the motor bushings and the graspers to enable suturing capabilities
- A new gripper design utilizes a new linkage to transfer force from the input shaft to the grippers. This linkage allows for a stronger gripping force compared to previous versions..
- A voice coil focus mechanism has been designed for the in vivo vision system. This allows for the lens of the camera to be moved towards or away from the imager by varying the current being run through wire coils. This method can be beneficial as it can save space compared to a motor driving the lens motion.
- A new insertion method for the robot was designed and tested using a mock robot. This constitutes a proof of concept demonstrating the possibility of inserting two separate halves of a robot into the peritoneal cavity and then assembling the robot into its operating form inside the cavity.
- Two concepts have been pursued to provide imaging capabilities for use in robotic surgery. The first concept involves developing a camera system that will be attached to the robot that utilizes a stereoscopic vision system. This stereoscopic vision system consists of two cameras for imaging and two LED light sources. The stereoscopic system provides for the possibility of a 3-dimensional vision system, which would give the surgeon increased functionality because of the additional depth perception achieved. The second concept utilizes current surgical laparoscopic technology, which is widely available in surgical rooms that perform laparoscopic surgery. A laparoscope, with a standard light, could be inserted through the insertion rod of the robot to provide a vision field of the robotic workspace. The availability and familiarity to surgeons of laparoscopes demonstrate some of the benefits of this method.
- A pair of digital imagers are being used in several ways to enhance the surgical robotic platform. The imagers have been integrated with a Hyundai W220S 22" Polarized 3D monitor. The result is a realistic, high definition, 3-dimensional visualization of the surgical environment that allows the surgeon to utilize depth perception while remotely operating the robot. The digital imagers are also being used to visually track the movement of the surgical robots arms. Preliminary testing indicates that the visual tracking is accurate within 1mm and is capable of significantly improving upon the accuracy of current motor-feedback-based tracking.
- Work in the design and implantation of a 5 degree of freedom (DOF) miniature in vivo surgical robot has continued. Components were redesigned to improve reliability and ease of assembly. Steps were introduced to improve the water tightness of the robot to prevent fluids from entering the robot while inside the body. In addition, a single incision insertion method protocol was introduced and

tested. This protocol allows a surgeon to step through robot orientations while he or she inserts each half of the robot into the abdominal cavity; these halves are then supported by a central insertion rod. Utilizing this setup in multiple porcine models, the surgical robot was successfully inserted into the abdominal cavity through a single incision; the robot was also able to manipulate tissue in all four quadrants. The central insertion rod allows for vision through the use of a standard laparoscope and lighting source commonly available in surgery rooms. While maintaining a seal for insulation, this laparoscope can be moved in 4 DOF to provide a large field of view.

- A completely new design of the kinematic arrangement of the robot was initiated, which allows for smaller overall size and the capability to insert the robot through a single incision.
- A new robot was designed and built using workspace information gathered from experimental workspace measurements taken in a porcine model. The robot was designed to have the reach and dexterity needed to perform multi-quadrant surgeries. The robot was designed to have the dexterity to use an "elbow up" or "elbow down" approach to the surgical site. The endpoint forces and speeds were designed to be similar to the previous robot, but have yet to be tested.
- A robot was designed and built for single-incision surgery. The robot was designed to be small enough to be inserted through a 1-inch incision, while having 5 DOF dexterity for better control of the robot by the surgeon. The prototype was designed with 80% plastic parts, reducing the cost and weight of the robot.
- We have developed a prototype of the new communication system that meets the following performance objectives:
 - Compact wiring. Reduction in the wiring complexity will increase the robot's agility while reducing the required incision size. We accomplish this objective by creating a local control system based on Programmable Interface Controller with digital signal processing capability or dsPIC. Communications between components are done through Inter IC or I2C bus.
 - Scalability. We have designed our communication system to be sufficiently responsive when up to 16 motors are used. To do so, we have created custom firmware that can efficiently translate user's commands to motor control signals.
 - Reliability. We have created a tool that allows developers to test and debug the control and communication software. The tool also provides interfaces to individually control each motor. It also reports the throughput performance so that developers can ensure timely responsiveness as the system is scaled toward the maximum load.
- A balance between decreasing the size of the robot and increased functionality within a confined workspace is being appropriately determined to allow for kinematic capabilities. Ex vivo, benchtop experiments were performed to confirm robotic capabilities such as lifting and positioning accuracy.
- A set of biocompatible polymers have been identified for potential use as overtubes in a controlled NOTES-based material delivery system. Experimental testing has highlighted advantages of certain materials. Rough design of the

- delivery system is underway and work in progress includes rapid prototyping of components for the system. CAD models for components have been and continue to be developed. We have brainstormed strategies for design of specialized helical driving members for the shuttling system and are now prepared for analytical modeling in support of this component.
- A set of suitable biocompatible polymers have been identified and an optimal material (silicone rubber) has been selected for use as an overtube for a NOTES-based material delivery system. With this material selected, a first generation delivery system (primary functional components only) has been designed and prototyped The current delivery system consists of three main components (overtube, helical driver and shuttle) and will function in a manner similar to a twist-end mechanical pencil. By rotating the driving spring, the shuttle will advance through the overtube in either direction depending on the direction of rotation.
- Preliminary prototype tests displayed undesirable levels of friction between the
 overtube and driving spring which caused the spring to advance through the
 overtube. Other results from testing showed a lack of strength in the peripheral
 features of the shuttle ,which lead their eventual failure. A finite element stress
 analysis of shuttle and its periphery in as-built conditions was performed to
 improved strength in future design revisions.

REPORTABLE OUTCOMES MANUSCRIPTS

Strabala, K., McCormick, R., Wortman, T., Lehman, A., Oleynikov, D., & Farritor, S. (2010). Workspace and force capabilities of a miniature multi-functional surgical robot. In *Proceedings of ASME 2010 5th Frontiers in Biomedical Devices Conference* (BioMed2010).

Wortman, T., Strabala, K., Lehman, A., Farritor, S., & Oleynikov, D. (2010, September). Design of a multi-functional miniature in vivo surgical robot. Abstract presented at the annual meeting (19th SLS Annual Meeting and Endo Expo 2010) of the Society of Laparoendoscopic Surgeons, New York City, NY, [manuscript in progress].

Wortman, T., Strabala, K., Lehman, A., Farritor, S., & Oleynikov, D. (2010). Laparoendoscopic single-site surgery using a multi-functional miniature in vivo robot, *The International Journal of Medical Robotics and Computer Assisted Surgery*, [In press].

EXPERIENCE/TRAINING SUPPORTED

Kyle Strabala, former UNL student, was accepted to a PhD program at Carnegie Mellon University subsequent to his work on this project.

Two UNL Students, Ryan McCormick and Tyler Wortman, were chosen to participate in the 2010 North American Summer School in Surgical Robotics, Seattle, Washington.

Albert Tsang, MD former clinical fellow at UNMC, was hired as a general surgeon at Toledo Hospital.

Manish Tiwari, MBBS, PhD former research fellow at UNMC, was selected for a residency program with the Department of Family Medicine at UNMC.

PRESENTATIONS

- 2010 ASME Frontiers in Biomedical Devices Conference (September, 2010)
- Technology was presented to visitors from Nebraska Office in Japan (September 9, 2010)
- 19th Society of Laparoendoscopic Surgeons Annual Meeting and Endo Expo (September, 2010)
- 2010 National McNair Scholars Undergraduate Research Symposium (August, 2010)
- Three medical students selected to participate in the Center for Advanced Surgical Technology's summer research program discussed miniature robotic research at the YEOH! (Youth Expression of Health) 8 Workshop (July 22, 2010)
- General Surgery Grand Rounds, University of Nebraska Medical Center (July, 2010)
- Project team participated in a TATRC visit from Colonel Poropatich, Dr. Carney, and Jessica Kenyon (June 9, 2010)
- Project technology was displayed in the laboratory of the Center for Advanced Surgical Technology for the UNMC Chancellor's Board of Counselor's meeting (April 26, 2010)
- Multifunctional Robot for Laparoendoscopic Single-Site Surgery was presented at the 12th World Congress of Endoscopic Surgery in Landover, MD (April 17, 2010) (see Appendix F)
- Display at Nebraska Robotics Exp at the Strategic Air and Space Museum (January 30, 2010)
- Shane Farritor was an invited participant in the cooperative robotic NOTES (roboNOTES) meeting sponsored by Dr. Broderick (January 26, 2010)
- Mini-robot presentation to Omaha area high school science administrators (January 8, 2010
- Presentation to UNMC Youth Learning Center comprised of students in grades 7-12 (February 20, 2010)
 - Mini-robot presentation to Omaha area high school science administrators (November 13, 2009)
 - *Your Doctor is a Robot* presentation by Dr. Oleynikov for general public audience in UNMC's Science Café (November 10, 2009)
 - Project was centerfold of fall 2009 edition of *UNMC Discover* magazine features miniature robotic surgical tools, www.unmc.edu/discover

FUNDING SOUGHT

Support: Current support

Investigators: Oleynikov, D., Farritor, S

Project Title: Supporting Surgical Options In Space

Source of Support: NASA

Total Award Amount: \$2,700,000

Performance Period: 09/30/10 - 09/29/12

Support: Submitted

Investigators: Farritor, S., Oleynikov, D., Lehman, A.

Project Title: Miniature In Vivo Robotic System for the Surgical Treatment of

Diverticular Disease

Source of Support: National Institute of Health (NIH)

Total Award Amount: \$578,098

Performance Period: 09/01/11 - 08/31/13

Support: Submitted

Investigators: Siu, K., Oleynikov, D.

Project Title: Adaptive Simulation Training for Prevention of Surgical Skill Attrition and

Surgical Errors

Source of Support: Agency for Healthcare Research & Quality (AHRQ)

Total Award Amount: \$1,050,000

Performance Period: 12/01/10 - 11/30/13

Support: Declined

Investigators: Nelson, C., Oleynikov, D.

Project Title: Advanced Robotic Tools for Natural Orifice Surgical Approaches

Source of Support: National Institute of Health (NIH)

Total Award Amount: \$394,912

Performance Period: 01/01/11 - 12/31/12

Support: Declined

Investigators: Nelson, C., Oleynikov, D.

Project Title: Advanced Robotic Tools for Single-Port Abdominal Surgery

Source of Support: National Institute of Health (NIH)

Total Award Amount: \$1,077,053

Performance Period: 01/01/11 - 12/31/12

Support: Declined

Investigators: Siu, K., Oleynikov, D.

Project Title: Virtual Training for Surgical Skills Source of Support: Adaptive Cognitive Systems

Total Award Amount: \$600,000

Performance Period: 01/01/11 - 12/31/11

Support: Declined

Principal Investigator: Siu, K., Oleynikov, D.

Project Title: CAESAR: Computer Automated Enhanced Support and Analysis for

Robotic Surgery

Source of Support: Intelligent Automation, Inc.

Total Award Amount: \$35,000

Performance Period: 08/01/10 - 01/31/11

Support: Declined

Investigators: Oleynikov, D., Farritor, S.

Project Title: Robotic Automation of Low-Level Surgical Tasks

Source of Support: Intuitive Surgical

Total Award Amount: \$50,000

Performance Period: 01/01/11-12/31/11

Support: Declined

Investigators: Siu, K., Oleynikov, D.

Project Title: Adaptive Simulation Training through Task Modeling for Prevention of

Laparascopic Surgical Skill Attrition

Source of Support: Adaptive Cognitive Systems

Total Award Amount: \$33,333

Performance Period: 07/01/10 - 03/31/11

INTELLECTUAL PROPERTY

Disclosure 1462, Application # 61/371,361 – Natural Orifice Material Delivery System for Surgery (Appendix E)

CONCLUSION

The specific aim of this proposal is to create a remotely controlled image-guided minirobot that can be placed entirely into the peritoneal cavity through the mouth to perform abdominal surgery and to demonstrate the feasibility of this approach in a non-survivable animal surgery. Progress thus far has resulted in a fully insertable robot capable of basic abdominal procedures. The robot is still too large for our purposes and lacks adequate, reliable control from a surgical perspective. A 6 DOF robot is currently under development. An additional degree of freedom is expected to increase the robot's dexterity and allow it to perform tasks not yet possible. In addition, a new 4 DOF robot is also under development. This robot will be significantly smaller and more robust than previous versions. Future benchtop and animal experimentation, expected to occur in quarters 5 through 8 of the project period, will provide the necessary data and experience to validate a working prototype in our progression toward successful autonomous robotic surgery.

REFERENCES

Dolghi, O., Strabala, K., Wortman, T., Goede, M., Farritor, S., & Oleynikov. (2010). Miniature in vivo robot for laparoendoscopic single-site surgery. *Annals of Surgery*, [Submitted].

Strabala, K., McCormick, R., Wortman, T., Lehman, A., Oleynikov, D., & Farritor, S. (2010). Workspace and force capabilities of a miniature multi-functional surgical robot. In *Proceedings of ASME 2010 5th Frontiers in Biomedical Devices Conference* (BioMed2010).

Wortman, T., Strabala, K., Lehman, A., Farritor, S., & Oleynikov, D. (2010, September). Design of a multi-functional miniature in vivo surgical robot. Abstract presented at the annual meeting (19th SLS Annual Meeting and Endo Expo 2010) of the Society of Laparoendoscopic Surgeons, New York City, NY.

Wortman, T., Strabala, K., Lehman, A., Farritor, S., & Oleynikov, D. (2010). Laparoendoscopic single-site surgery using a multi-functional miniature in vivo robot, *The International Journal of Medical Robotics and Computer Assisted Surgery*, [In press].

APPENDICES

Appendix A: Wortman, T., Strabala, K., Lehman, A., Farritor, S., & Oleynikov, D. (2010). Laparoendoscopic single-site surgery using a multi-functional miniature in vivo robot, *The International Journal of Medical Robotics and Computer Assisted Surgery*, [In press].

Appendix B: Dolghi, O., Strabala, K., Wortman, T., Goede, M., Farritor, S., & Oleynikov. (2010). Miniature in vivo robot for laparoendoscopic single-site surgery. *Annals of Surgery*, [Submitted].

Appendix C: Wortman, T., Strabala, K., Lehman, A., Farritor, S., & Oleynikov, D. (2010, September). Design of a multi-functional miniature in vivo surgical robot. Paper presented at the annual meeting (19th SLS Annual Meeting and Endo Expo 2010) of the Society of Laparoendoscopic Surgeons, New York City, NY. [Abstract, manuscript in progress].

Appendix D: Strabala, K., McCormick, R., Wortman, T., Lehman, A., Oleynikov, D., & Farritor, S. (2010). Workspace and force capabilities of a miniature multi-functional surgical robot. In *Proceedings of ASME 2010 5th Frontiers in Biomedical Devices Conference* (BioMed2010).

Appendix E: Disclosure 1462, Application # 61/371,361 – Natural Orifice Material Delivery System for Surgery [Report of Inventions and Subcontracts].

Appendix F: Strabala, K., Wortman, T., Lehman, A., Wood, N., Tiwari, M., Goede, M., Farritor, S., & Oleynikov, D. (2010). Multifunctional robot for laparoendoscopic single-site surgery. Abstract presented at the annual meeting (SAGES) of the Society of American Gastrointestinal and Endoscopic Surgeons, Landover, MD. [Abstract].

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Accepted: 22 September 2010

Laparoendoscopic single-site surgery using a multi-functional miniature in vivo robot[†]

Tyler D. Wortman¹ Kyle W. Strabala¹ Amy C. Lehman¹ Shane M. Farritor¹ Dmitry Oleynikov²*

¹University of Nebraska-Lincoln, N104 Walter Scott Engineering Center P.O. Box 880656, Lincoln, NE 68588-0656, USA

²University of Nebraska Medical Center, 983280 Nebraska Medical Center Omaha, NE 68198-3280, USA

*Correspondence to: Dmitry Oleynikov, University of Nebraska Medical Center, 983280 Nebraska Medical Center, Omaha, NE 68198-3280, USA. E-mail: doleynik@unmc.edu

†Presented at the 2010 MIRA Meeting.

Abstract

Background Existing methods used to perform laparoendoscopic singlesite surgery (LESS) require multiple laparoscopic tools that are inserted into the peritoneal cavity through a single, specialized port. These methods are inherently limited in visualization and dextrous capabilities by working through a single access point. A miniature in vivo robotic platform that is completely inserted into the peritoneal cavity through a single incision can address these limitations, providing more intuitive manipulation capabilities and improved visualization.

Methods The miniature in vivo robotic platform for LESS consists of a multifunctional robot and a remote surgeon interface. The robot has two arms and specialized end effectors that can be interchanged to provide monopolar cautery, tissue manipulation, and intracorporeal suturing capabilities.

Results This robot has been demonstrated in multiple non-survival procedures in a porcine model, including four cholecystectomies.

Conclusion This study demonstrates the effectiveness of using a multifunctional miniature in vivo robot platform to perform LESS. Copyright © 2010 John Wiley & Sons, Ltd.

Keywords •

Introduction

The benefits of performing surgical procedures using minimally invasive 100 techniques rather than traditional open surgery are well established, including 101 reduced post-operative pain, shortened hospital stays with decreased costs, 102 improved cosmetic results and decreased mortality numbers (1-7). These benefits have contributed to establishing laparoscopy as the standard of care 104 for many abdominal procedures (8). Since the introduction of laparoscopic 105 techniques for cholecystectomy, almost 100% of these procedures are 106 performed using minimally invasive surgery (9). Although replacing one 107 large incision with three to five small incisions greatly improves patient 108 outcomes, surgical procedures performed using minimally invasive techniques 109 are surgically challenging. Traditional laparoscopic surgery relies on the use of 110 long, rigid tools with a two-dimensional laparoscope providing visualization. 111 Learning to use these tools that reduce dexterity, while also adapting to the 112lack of tactile feedback, fulcrum effect and two-dimensional imaging leads to 113a learning curve for more technically difficult surgeries (2,10,11).

Continuing focus remains on reducing the invasiveness of surgical procedures through limiting the number and size of incisions. Creating 116 fewer incisions improves patient recovery, reduces post-operative pain, and also helps to reduce the number of adhesions that form internally, making

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future surgeries easier (9,12). New techniques, including 2 laparo-endoscopic single-site surgery (LESS), and natural 3 orifice translumenal endoscopic surgery (NOTES) have 4 been used with virtually scarless results (6,8,13,14). LESS 5 uses a single specialized port inserted transumbilically, 6 creating a new scar that is hidden in the natural umbilical 7 scar (15). Existing methods for performing LESS use 8 multiple articulating, bent, or flexible laparoscopic tools that are inserted into the peritoneal cavity through a 10 single specialized port (16). Most NOTES procedures 11 require the introduction of a flexible multi-channel endoscope through a natural orifice, such as the rectum, 13 throat or vagina, leaving no external scars (14). Both LESS and NOTES methods for performing minimally 15 invasive surgery are inherently limited in visualization and dexterous capabilities by working through a single 17 access point because It is difficult to have multiple 18 instruments passing through a single insertion point while 19 also maintaining adequate manipulation and visualization 20 capabilities. These limitations are enhanced for NOTES 21 procedures where tools must also be flexible for insertion through the complex geometry of the natural lumen. This 23 has contributed to NOTES not yet being as widely adopted as LESS (12,16). 24 25

New technologies are needed to overcome the challenges associated with minimally invasive techniques so that the patient benefits can be realized for more complex surgical procedures. As technology has developed and improved, there has been increased interest in the use of robotics to improve the outcomes of surgery and to make procedures more precise (17,18). Many of these systems are externally actuated and utilize a master-slave interface. The DaVinci® Surgical System (Intuitive, Sunnyvale CA) is a commercially available robotic system that improves dexterity and visualization through the use of articulating Endo-wrists[™] and threedimensional imaging. When using this system, the surgeon sits at a remote control console while the arms of the robot are positioned above the patient at the operating table. Limitations of this system include difficulties in repositioning the patient, arm collisions, size, and high cost (19,11). There are also research efforts targeting smaller, dexterous robots for surgical tool guidance. Research systems include the CURES, MC²E, Raven, and CoBRASurge robots (20-23). Commercial products for laparoscope guidance are also available, including ViKY (Endocontrol), Freehand and EndoAssist (Prosurgics), LapMan (Medsys), and SoloAssist (AKTORmed) (24–27).

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An alternative approach to externally actuated systems is the use of miniature robots that can be completely inserted into the peritoneal cavity through a single incision or a natural orifice to perform a surgical procedure. These devices are not constrained by working through the insertion incision once completely inside the peritoneal cavity. For example, a transabdominal magnetic anchoring and guidance system (MAGS) that includes intra-abdominal cameras and retraction instruments is currently being developed for NOTES and LESS applications (28). These devices are attached

and positioned within the peritoneal cavity using the interaction of magnets housed in the robot with external handheld magnets. Similarly, insertable monoscopic and stereoscopic imaging devices with multiple degrees of freedom are also being developed for minimally invasive surgery (29). Previous research within our group has focused on the development of miniature in vivo robotic devices including mobile camera and biopsy robots (30, 31), magnetically mounted imaging robots (32), and dexterous robots (33). Continued research and development of smaller and more technically capable surgical robotic assistants will shape the future of minimally invasive surgery.

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Materials and Methods

The robotic platform designed specifically for laparoendoscopic single-site surgery (LESS) consists of a multifunctional robot and a remote surgeon interface. This robot is designed to be inserted through a single incision and to be contained completely within the peritoneal cavity. The miniature dexterous in vivo robot, shown in Figure 1, consists of two arms connected to a main body segment. The main body of the robot is composed of three modules. These modules can be independently inserted through a single incision and then assembled once inside the peritoneal cavity to provide surgical capabilities. Intracorporeal assembly is completed by utilizing control rods to line up each module and attaching a custom fastener to lock the modules in place. This task takes an average of ten minutes to complete but has proven to be difficult due to the limited space within the peritoneal cavity. Following assembly of the robot, a mounting rod is introduced through the insertion incision and mated to the center module to support the robot within the peritoneal cavity. The mounting rod is supported by an external support system that is mounted to the rails of the operating table. Gross positioning of the robot within the peritoneal cavity can be 100 accomplished by adjusting the depth and angle of the 101support rod.

Each outer module of the robot body, shown in Figure 2, is connected to an arm at a two-degree of freedom joint. 104 The shoulder joint links consist of a distal joint providing 105 yaw, and a proximal joint providing pitch. Each arm 106 consists of a two-degree of freedom rotational elbow 107 joint. Specialized end effectors on each forearm can be 108 interchanged to provide tissue manipulation, monopolar 109 cautery, and intracorporeal suturing capabilities. Each 110 outer module is connected to a center module that 111 contains two cameras. These cameras can provide 112 stereoscopic visualization with panning and tilting. An 113 ultra-bright LED is also contained in the center module to 114 provide on-board lighting.

The robot joints are independently controlled using a 116 proportional-integral-derivative (PID) control method, 117 with actuation provided by coreless permanent magnet 118

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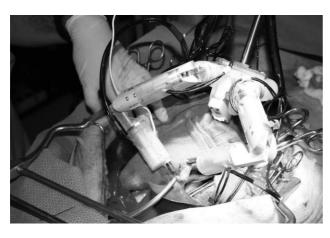


Figure 1. Miniature in vivo surgical robot performing cholecystectomy

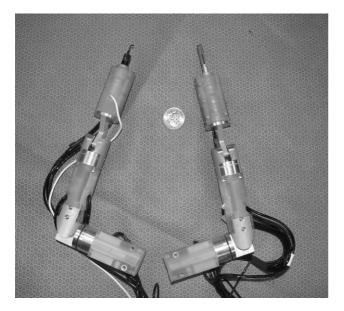


Figure 2. Separated robot outer arm modules

direct current motors with magnetic encoders. These motors are housed within the arms and body of the robot. Two external CompactRIO[™] controllers and chassis (National Instruments, Austin, TX) are tethered to the motors. They are driven using a direct current servo drive with encoder interface. LabVIEW[™] software (National Instruments, Austin, TX) is used to interface with the motor controller and drivers. This software provides capabilities including, locking the robot position, clutching, motion playback, and motion scaling.

The surgeon control interface, shown in Figure 3, consists of a monitor, two controllers, and a foot pedal. Control of the robot arms is accomplished using two PHANTOM Omni® (SensAble, Woburn, MA) devices. Buttons on the grip of the controllers allow for activation of the graspers and cautery. Both controllers utilize haptic feedback to define the workspace of the robot. When the robot has reached the limit of its workspace, the controllers provide feedback resisting any further motion. A triple action foot switch provides

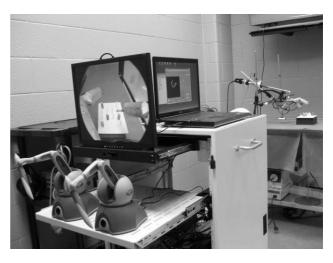


Figure 3. Remote surgeon interface

clutching to reset the position of the controllers in 60 the workspace, and also locking of the robot. Video from the cameras onboard the robot is displayed on a standard television screen located between the two controllers.

The multi-functional robot platform has been prototype tested in four non-survival cholecystectomies in a porcine model at the University of Nebraska Medical Center. All experimental protocols were approved by the institutional review committee. The robot was supported above the animal using the external support assembly described previously.

The robot was then positioned within the proper workspace for performing a cholecystectomy. The surgeon controlled the robot from the control console located remotely within the operating room. The procedure was then performed similarly to a standard laparoscopic cholecystectomy. The grasper end effector was extended to grasp the cystic duct and lifted while the cautery end effector performed tissue dissection. This stretch and dissect task was performed iteratively until a full cholecystectomy was completed, as shown in Figure 4. Stapling of the cystic duct and supplementary retraction were performed using standard laparoscopic tools.

Results

The four non-survival animal model cholecystectomies performed using the multi-functional robot platform demonstrated the ability to use a miniature robotic platform to perform laparoscopic surgery. During all four procedures, a complete cholecystectomy was performed. In each case, the robot was placed within the peritoneal cavity through a single one inch incision. Surgeons were unable to assemble the robot completely due to technical problems involving limited space. Therefore, a large transabdominal incision was made to provide access to the peritoneal cavity and the robot was suspended in an open fashion.

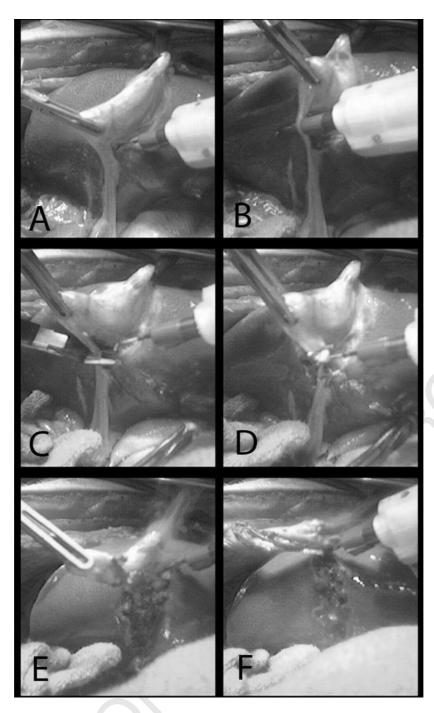


Figure 4. (A) Grasping of cystic duct; (B) separation of cystic duct; (C) stapling of cystic duct; (D) dissection of cystic duct; (E) tissue dissection; (F) completion of cholecystectomy

The first two procedures used a Bovie® cautery that proved to be weak and ineffective. Each complete cholecystectomy procedure took two hours. The last two procedures utilized a monopolar hook cautery that was much more effective. The complete cholecystectomy procedure was reduced to ten minutes.

The addition of monopolar electrosurgery on this robot, compared with Bovie® cautery used with earlier robot prototypes, allows for much more effective cauterizing capabilities. The Bovie® cautery was prone to failure and needed to be replaced often. Although the monopolar cautery proved to be superior, issues with wiring

insulation and current surges caused major problems in the development of this feature.

Discussion

Monopolar cautery in combination with an increased workspace and improved speed contributed to improvements in operating times required for performing a cholecystectomy compared with previous generations of the robot. Further, the use of the PHANTOM Omni® (SensAble, Woburn, MA) as part of the surgeon interface

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improved the surgeon's ability to perform precise surgical 2

Although these procedures were successful, limitations must be addressed to allow the robot to perform surgery through a single incision. The primary limitation is the size of the current prototype. The diameter of the robot is small enough to be introduced through a LESS port, but the length of the arms needs to be decreased. Another limitation is that the current kinematic arrangement of the robot forces the arms to come into contact with the walls of the peritoneal cavity while trying to reach certain points within the robot workspace. These limitations are being addressed in the continuing iterations of the robot design.

Laparoendoscopic single-site surgery is currently constrained by the existing instrumentation that limits the surgeon's ability to visualize and dexterously manipulate within the surgical environment. The existing instruments for these procedures are based on modified laparoscopic tools or a flexible endoscopy platform. All of these instruments are still limited in dexterity due to the confined insertion space. Therefore, LESS is dependent on the development of devices that improve these limitations.

This multi-functional miniature in vivo robot platform provides a completely insertable robot that enables the performance of advanced surgical tasks while improving triangulation. This robot provides a stable platform that includes sufficient visualization, dexterity, and speed along with the ability to perform complex tasks from multiple orientations and workspaces within the peritoneal cavity. The use of interchangeable end effectors suggests the feasibility of using the robot for multiple tasks. Current improvements to the multi-functional robot are focused on reducing the size of the robot while maintaining adequate speed, strength, and dexterity.

Acknowledgements

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MINIATURE IN VIVO ROBOT FOR LAPAROENDOSCOPIC SINGLE-SITE SURGERY

Oleg Dolghi, M.D**, Kyle W. Strabala, M.S*, Tyler D. Wortman, B.S*, Matthew R. Goede, M.D**, Shane M. Farritor, Ph.D*, Dmitry Oleynikov, M.D**

University of Nebraska – Lincoln, College of Engineering*

University of Nebraska Medical Center, Department of Surgery**

Corresponding author:

Dmitry Oleynikov, M.D 985126 Nebraska Medical Center Omaha, NE 68198-5126 Phone: (402) 559-4581

Fax: (402) 559-7750

Email: doleynik@unmc.edu

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Running Head: MINIATURE IN VIVO ROBOT

STRUCTURED ABSTRACT

Objective: To develop a multi-dexterous robot capable of generating the required forces and speeds to perform surgical tasks intra-abdominally.

Summary Background Data: Current laparoscopic surgical robots are expensive, bulky, and are fundamentally constrained by a small entry incision. A new approach to minimally invasive surgery places the robot completely within the patient. Miniature in vivo robots are the future when it comes to overcoming current laparoscopic constraints such as dexterity, orientation and visualization.

Methods: A collaborative research group from the Department of Surgery at the University of Nebraska Medical Center and the College of Engineering at the University of Nebraska - Lincoln designed and built a surgical robot prototype capable of performing specific surgical tasks within the peritoneal cavity. The robot was built primarily to allow for better visualization and articulation as well as better triangulation control and ability of complex movements.

Results: A robotic platform consisting of a miniature in vivo robot and a remote surgeon interface has been designed and built. The basic robot design consists of two arms each connected to a central body. Each arm has three degrees of freedom and rotational shoulder and elbow joints. This combination allows a surgeon to grasp, manipulate, cauterize, and perform intracorporeal suturing. The robot's workspace is a hollow hemisphere with an inner radius of 75 mm and an outer radius of 205mm. Its versatility was demonstrated by four procedures performed in a porcine model: cholecystectomy, partial colectomy, abdominal exploration, and intracorporeal suturing.

Conclusions: Miniature in vivo robots have the potential to address limitations of using articulated instrumentation to perform advanced laparoscopic surgical procedures. Once inserted into the peritoneal cavity, the robot provides a stable platform for visualization with sufficient dexterity and speed to perform surgical tasks from multiple orientations and workspaces.

INTRODUCTION

The use of minimally invasive surgical techniques has become the standard of care for many routinely performed surgical procedures [1-7]. However, laparoscopic procedures remain constrained due to limitations in accessing the surgical target and working with coaxial tools. These limitations are intensified when working through a single insertion point; instrument collisions frequently occur internally and externally, which limits tool triangulation, application of off-axis forces, and the size of the instruments [8, 9]. Insertion of additional ports is associated with postoperative pain, wound infection, and hernia formation [10-12].

Developments within surgical robotics attempt to mitigate the constraints of minimally invasive surgery by improving visualization and dexterous manipulation capabilities. The Da Vinci Surgical System® (Intuitive Surgical, Sunnyvale, CA) is a commercially available telerobotic system that enables a surgeon, located at a remote workstation, to control multiple robotic arms that hold laparoscopic tools. This system addresses the limitations of Minimally Invasive Surgery through wristed articulating end effectors, tremor filtering, and motion reversal correction [13-15]. The system remains limited by its high cost, large size, and the diminished impact of dexterous improvements for performing less complex laparoscopic procedures.

Our research has been focused on the development of miniature in vivo robotic devices including mobile camera and biopsy robots [16, 17], magnetically mounted imaging robots [18], and dexterous robots [19-25]. To provide for greater flexibility, visualization, orientation, more efficient instrument usage, and to further reduce morbidity rate and cost, we have built a fully functional, multi-dexterous robot. This prototype is capable of generating the forces and speeds required to perform specific surgical tasks within the peritoneal cavity, such as suturing; cauterizing; and tissue manipulation.

MATERIALS AND METHODS

A collaborative research group from the Department of Surgery at the University of Nebraska Medical Center and the College of Engineering at the University of Nebraska - Lincoln designed and built a surgical robot prototype capable of performing specific surgical tasks within the peritoneal cavity. The robotic prototype was built primarily to allow for better visualization and articulation as well as better triangulation control and ability of complex movements during the routine surgical procedures.

The basic robot design consists of two arms each connected to a central body as shown in Figure 1. The two arms are 190 mm in length and have a diameter of 26 mm. Each arm has three degrees of freedom rotational shoulder and elbow joints. These joints allow the surgeon to position the instrument tip of each arm at any point in the robot's workspace as well as rotate the instrument around its long axis (Figure 2). A PID (proportional-integral-derivative) method controls each of the robot's joint with magnetic encoders. The motors are embedded within the arms and body of the robot. In this design, the location of the elbow joint is determined by the position of the tool tip, and thus cannot be controlled by a surgeon.

The body of the robot contains a mounting assembly and consists of two modules that can be inserted through a single incision one-by-one and assembled inside the abdominal cavity. Control rods are used to align the parts and a custom fastener secures the parts in place. Assembly is complicated by the limited space of the peritoneal cavity and on average takes approximately ten minutes. After the robot is assembled, a mounting rod is inserted through the incision and attached to the body to provide better support inside the abdominal cavity. Depth and angle of the mounting rod can be adjusted to secure gross positioning of the robot.

Each forearm is fitted with specialized grasper or cautery end effectors. These end effectors can be interchanged depending on the task being performed. This combination allows a surgeon to grasp, manipulate, and cauterize tissue. Laparoscopic needle drivers are used, in place of the cautery and grasper end effectors, for intracorporeal suturing,

The surgeon interface, located remotely within the operating room, consists of a video display, a foot pedal for locking and clutching, and two PHANTOM Omni® (SensAble, Woburn, MA) devices for manipulation of the robot arms (Figure 3). The workspace of the robot is determined by both controllers, which rely on tactile feedback. When controllers face motion resistance, the robot's workspace had been used to its full potential. A clutch activated by a triple action foot switch resets controllers and secures the position of the robot.

Four procedures were performed on a porcine model for comparison between the robotic platform and LESS using traditional tools and techniques. All procedures and experimental protocols were approved by the appropriate institutional review committee, including the Institutional Animal Care and Use Committee, and meet the guidelines of the responsible governmental agencies.

RESULTS

This surgical robot prototype was used in three, non-survival porcine experiments. Four procedures were performed: cholecystectomy, partial colectomy, abdominal content exploration, and intracorporeal suturing. The porcine model was prepared for surgery and the robot was mounted above the incision via a rod attached to the rails of the operating table, as shown in Figure 4. A single one-inch incision was used to introduce the robot within the abdominal cavity in all the cases. A standard laparoscopic camera was inserted through an additional port for

visualization. A surgeon, seated at the user interface, controlled the robot to perform the procedures.

First, the miniature robot was inserted and positioned to perform a robot cholecystectomy. The procedure was performed using a standard single incision laparoscopic approach with a laparoscopic port placed at the umbilicus. The robot was fitted with a grasper on the left arm and electrocautery on the right arm to perform the procedure. The left arm was used to grasp and manipulate tissue, while the right arm was used to cut and cauterize tissue. The procedure continued through iterations of this stretch and dissect task. The surgeon at the console, located remotely within the operating room, positioned the robotic arms within the workspace. Cystic duct was stapled with the help of laparoscopic tools, which are also used for supplementary retraction. Overall, the procedure is similar to a standard laparoscopic cholecystectomy. On average, the procedures took eight minutes. We report good visual control and the ability to move the robot arms freely. The robot allowed the surgeon to triangulate and manipulate tissue in a laparoscopic manner that is familiar to most surgeons. Because the tools where positioned at either end of the laparoscope, the surgeon had no collision between instruments and the shoulder and elbow joint allowed for wrist like manipulation.

The robot was also used to perform intracorporeal suturing. A gastrotomy was created and the robot's arm with a second grasper was introduced. The suture was then picked by the robot and gastrotomy was sutured close (Figure 5). The elbow and shoulder joint significantly simplified this procedure allowing the surgeon to tie the knot easily.

The robot was then repositioned over the sigmoid colon in the left pelvis of the swine and was used, with one grasper hand and one cautery hand, to dissect out the mesentery of the sigmoid colon down to the pelvis. As vessels are small, they were cauterized carefully. The colon

was mobilized from its lateral attachments (Figure 6). The robot was used to assist in a placement of a standard stapler to transect a sigmoid colon. The specimen was then removed and the colon was transected with an EEA stapler in a standard fashion. Robotic mobilization was accomplished easily.

DISCUSSION

A robotic interface for complex manual tasks through small incisions was pioneered by Intuitive Surgical (Sunnyvale, CA) almost two decades ago. It has allowed surgeons to perform complicated pelvic suturing maneuvers with relative ease where standard laparoscopic techniques would make this an extraordinarily difficult procedure [13-15].

Miniature robots have been a new addition to the world of surgery; they have the potential to bring about changes in modern surgery as did laparoscopic surgery in the 1980s. The recent evolution of innovative technology in robotics is encouraging. There have been ongoing international studies to further advance the scope of miniature, surgical robots. Such studies have found application in a variety of subspecialties within surgery. Some of the advantages of miniature robots include increased precision, decreased blood loss, less pain, and quicker healing time.

The introduction of mini-robots over the last few years may have a tremendous impact on the future of minimally invasive surgery. In particular, miniature robots have enabled surgeons to overcome challenges of eye hand dissociation, replaced a two dimensional field of view with three dimensional, and improved dexterity by increasing the freedom of working instruments [20-22].

Current robots are bulky and require significant space in an already crowded operating room. Alternatively, miniature robots are inserted entirely into the peritoneal cavity for

laparoscopic and natural orifice transluminal endoscopic procedures. These robots can provide vision and task assistance without the constraints of entry-port incisions. Miniature robots are easily deployed in a variety of environments. These robots are smaller, smarter, and less expensive. They can be controlled remotely and by telepresence.

The pan tilt imaging robot has been used to assist in a standard laparoscopic cholecystectomy in a porcine model and a laparoscopic nephrectomy and prostatectomy in a canine model. This miniature robot provides an enhanced view of the operating field from various angles during laparoscopic cholecystectomy. It allows for rotation of approximately two independent axes, allowing it to pan 360° and tilt 45°. Increased rotation enhances visualization and depth perception of the abdominal cavity in surgical procedures. Independent motors actuate the robot's tilting lever and provide a panning motion. The entire assembly rests on a small ball bearing that is attached to the base and is externally controlled by a joystick.

This technology will be a significant step forward, if it proves to be advantageous compared to the existing robots while also retaining the benefits of conventional instrumentation. First, it is important for a mini-robot to be easily repositioned as necessary. Secondly, surgical pain should be minimized by elimination of the possibility of multiple ports. Lastly, visibly unappealing surgical scars should be minimized further by utilizing a small, single incision. Laparoendoscopic Single-Site Surgery (LESS) is currently constrained by the existing instrumentation that limits the surgeon's ability to visualize and dexterously manipulate within the surgical environment. The existing instruments for these procedures are based on modified laparoscopic tools or a flexible endoscopy platform. All of these instruments are still limited in dexterity due to the confined insertion space and inability to triangulate.

There are a number of technical limitations that need to be addressed. The robot is too large and needs to have its joints narrowly positioned to improve its reach. We had to reposition the robot each time that we needed to move from one procedure to another and several times within each procedure. In the future, the issue of repositioning could be managed with a remotely controlled robotic arm or by an active, bedside assistant. Because of the single incision nature of the insertion, it was often difficult to get the robot inside through a reasonably sized hole; we had to enlarge our incision and subsequently used the robot as the only operation guide. A smaller and more robust robot would be able to perform surgeries through a single incision without these limitations.

The robotic devices are undergoing continuous improvements. One of the fundamental modifications is to reduce the size of the robot. Miniature robots are more agile inside the abdominal cavity than the current generation of large robots. Because they are small, multiple robots can be deployed given a specific task. The possibility of telesurgery can be realized with miniature surgical robots.

Future plans involve developing smaller and more agile robots with additional degrees of freedom for more dexterous movement. Such additional freedom of movement will enable the surgeon to approach an area from several directions to avoid tissue-robot collisions and object occlusion.

It remains to be seen whether this new technology will be a viable alternative to traditional laparoscopic approaches. Its adoption would force surgeons to gain new skills to perform complex procedures. It has the potential to be a major innovation in surgery of the 21st century, provided it is safe for patients and we get equal or better results in comparison to the techniques we are replacing.

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LEGEND

Figure1: Current robotic design. This prototype consists of two arms connected to a central body piece.

Figure 2: Schematic representation of prototype design. Each arm has 3degrees of freedom rotational shoulders and elbow joints.

Figure 3: Remote surgeon interface consisting of two Phantom Omni controllers, a 3-switch foot pedal, and a video display.

- **Figure 4**: The robot is mounted above the incision via a rod attached to the rails of the operating table.
- Figure 5: Suturing a gastrotomy in a porcine model using the robot with needle drivers.
- Figure 6: Colon dissection and mobilization in a porcine model.

DESIGN OF A MULTI-FUNCTIONAL MINIATURE IN VIVO SURGICAL ROBOT

Tyler D. Wortman BS, Kyle W. Strabala MS, Amy C. Lehman MS,
Shane M. Farritor PhD, Dmitry Oleynikov MD
University of Nebraska-Lincoln, University of Nebraska Medical Center

The widespread adoption of the LaparoEndoscopic Single-Site surgery (LESS) for complex surgeries is dependent on the development of devices that provide a stable multi-tasking platform. Existing methods for performing LESS are limited because of the mechanics of using multiple instruments inserted through a single incision. This results in limited dexterity and poor triangulation and visualization. Prior research within our group has demonstrated the feasibility of using a completely insertable robotic platform consisting of a two-armed miniature in vivo robot and a remote surgeon interface to address these limitations. Current prototypes are too large to perform a laparoscopic surgery using a purely LESS approach. However, this study presents the kinematic improvement of the multi-functional miniature in vivo robot with the goal of reducing the overall size of the robot. Measurements of the in vivo workspace required by the robot for performing cholecystectomy have been performed during multiple non-survival procedures in a porcine model. The actual motion of the robot, as determined from the motor encoders, was recorded during surgery using LabVIEW™ (National Instruments, Austin, TX) software. This information was used with a kinematic analysis of the existing robot to determine the position of both the cautery and grasping end effectors throughout the procedures. The design of the robot was then kinematically improved to operate within the determined workspace. These studies have contributed to significantly reducing the size of the multi-functional robot to better enable the performance of surgical procedures through a single incision.

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WORKSPACE AND FORCE CAPABILITIES OF A MINIATURE MULTI-FUNCTIONAL SURGICAL ROBOT

Kyle W. Strabala, Ryan M. McCormick, Tyler D. Wortman, Amy C. Lehman and Shane M. Farritor
University of Nebraska – Lincoln
Lincoln, NE 68588
Email: kstrabala@gmail.com

Dmitry Oleynikov University of Nebraska Medical Center Omaha, NE 68198

INTRODUCTION

This paper describes the capabilities of a miniature multi-functional *in vivo* robot designed and developed for Laparoendoscopic Single-Site Surgery (LESS). The paper outlines several competing design criteria including robot size, workspace volume, endpoint speeds, and endpoint forces. In this paper, the robot is evaluated according to these criteria. The workspace is described and the maximum no-load endpoint speeds and maximum attainable endpoint forces are presented. Finally, the robot capabilities are discussed, related to medical applications, and demonstrated in an animal surgery.

BACKGROUND

LESS is the use of a single small incision to perform surgeries which would otherwise be performed with a large incision or multiple smaller incisions. LESS offers several advantages to the patient over other more traditional surgeries including a reduced risk of infection, faster recovery time, and a less painful recovery. However, LESS provides several additional challenges to the surgeon including restricted working space, restricted vision, and unintuitive control of surgical tools.

METHODS

A miniature surgical robot was designed and developed to eliminate the challenges of LESS by providing a dexterous multi-functional platform for surgical tools with an intuitive control interface. To perform LESS with the robot, the robot is inserted into the abdominal cavity through an incision and then the abdomen is insufflated with CO₂. Insufflation

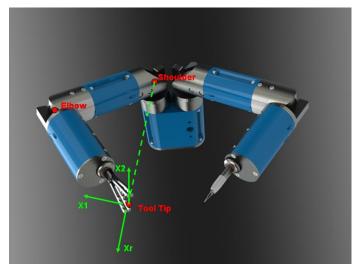


FIGURE 1. ROBOT DESIGN AND AXIS ORIENTATION

provides sufficient space for the robot to perform multiple complex tasks including tissue manipulation, electrocautery, and suturing.

The robot can be described as a torso with two arms, as shown in Figure 1. Each arm is 205 mm long and consists of two links and an end-effector, where the end-effector has four degrees of freedom (DOF), three translational DOF plus one rotational DOF. The end-effector is one of several

interchangeable surgical tools including tissue grippers, needle graspers, and electrocautery tips.

The maximum endpoint force the robot can apply was calculated from measurements of the maximum joint torques using a load cell. Three motors influence the maximum endpoint force possible. With the measured maximum torques of these motors and knowing the kinematics of the robot, the maximum endpoint forces were calculated at positions around the robot's workspace. At each position, three tangent forces were calculated indicating the maximum radial and two tangential forces at that position as shown in Figure 1. The forces were calculated at radial points equally spaced from the shoulder joint. The maximum joint torques were calculated using a 2 lb Entran load cell.

The maximum endpoint speeds the robot could attain were determined at positions around the robot's workspace. At each position, three tangent speeds were calculated indicating the maximum radial and two tangential speeds at that position as shown in Figure 1. Similar to the force measurements, the speeds were calculated at radial points equally spaced from the shoulder joint. To calculate the maximum speeds, the robot was moved around its workspace with step inputs and the maximum angular speeds of each joint were determined. Then, using the robot kinematics combined with the maximum joint speeds, the maximum attainable endpoint speeds were calculated. The angular speeds were calculated using the motor encoder counts.

To test its performance, the robot was used to perform a cholecystectomy in a live porcine model. This prototype was too big for LESS, so an open surgery on the gall bladder was setup as shown in Figure 2. A surgeon operating two Phantom Omnis (SensAble) controlled the movement of the robot. The left arm of the robot was equipped with a tissue grasper and the right arm was equipped with a monopolar electrocautery hook. The cholecystectomy consisted of 3 stages: isolation of the cystic duct and artery, stapling and cutting of the cystic duct and artery, and dissection of the gall bladder away from the

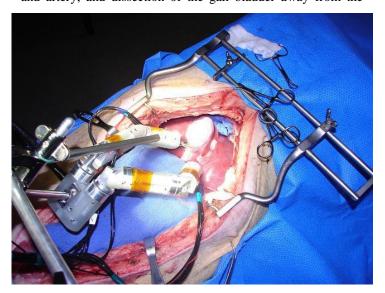


FIGURE 2. PICTURE OF ROBOT SETUP TO PERFORM A CHOLECYSTECTOMY

liver bed. The stapling was performed by an assistant using a manual laparoscopic tool.

Several data were recorded from the surgery including video of the surgical field, video from the endoscope used by the surgeon, the target position of the robot's tool tips as determined by the controllers held by the surgeon, and the position of the robot's tool tips as estimated from the motor encoder counts. From these data, the workspace and speeds used during the surgery were analyzed.

RESULTS

A robot was designed and developed for LESS. The tool tip speed and force limits were experimentally determined at various radii from the robot's shoulder joint. Finally, the robot was used to perform a cholecystectomy in a porcine model.

The robot's workspace is considered as the volume of space where the tool tip can travel and is bounded by the minimum and maximum attainable tool tip radii from the shoulder joint. The minimum attainable radius was 75 mm and the maximum attainable radius was 205 mm. This gives a workspace that looks like a hallow hemisphere with a wall thickness of 130 mm.

The maximum attainable speed was calculated at regular intervals in the robot's workspace varying from the minimum radius to the maximum radius from the shoulder joint. The maximum speed of the tool tip increased in the X1 and X2 directions and decreased in the Xr direction as the radius increased from the minimum radius to the maximum radius, as shown in Figure 3. The average maximum speed was 750 mm/s, 740 mm/s, and 430 mm/s in the Xr, X1, and X2 directions, respectively.

The maximum attainable force at the tool tip was calculated at regular intervals in the robot's workspace varying from the minimum radius to the maximum radius from the shoulder joint. The maximum attainable force at the tool tip decreased in each direction from the minimum radius to the maximum radius, as shown in Figure 3. The median maximum force the robot could apply was 3 N, 3 N, and 11 N in the Xr, X1, and X2 directions, respectively.

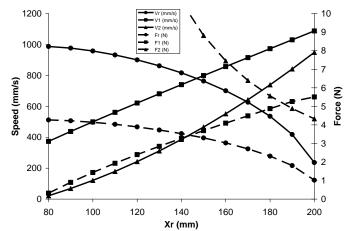


FIGURE 3. MAXIMUM SPEED AND FORCE OF TOOL TIP VERSUS TIP DISTANCE FROM SHOULDER

The robot was used to perform a cholecystectomy in a live porcine model. The pig was prepared for an open cholecystectomy and the gall bladder was removed. Using two hand-held controllers, the surgeon isolated the cystic duct and artery, cut the cystic duct and artery, and dissected the gall bladder away from the liver bed. An assistant with a manual laparoscopic tool stapled the cystic duct and artery before the surgeon cut it. The operation took 6 minutes for the surgeon to remove the gall bladder with the robot.

The positions of the target state, as obtained from the surgeon's hand-held controllers, and the robot tool tips, as estimated from the motor encoder counts and robot kinematics, were recorded during the gall bladder surgery. The left tool tip was a tissue grasper while the right tool tip was an electrocautery hook for cutting. From these data, the workspace size and speeds used during the surgery were calculated. 90% of the tool tip motions were within 17x33x57 mm and 17x21x22 mm volumes for the left and right tool tips, respectively. The left tool tip worked in a larger workspace than the right tool tip. The maximum speed obtained during the surgery was 120 mm/s and 100 mm/s for the left and right arms, respectively. The average speed was 4 mm/s and 14 mm/s for the left and right arm, respectively.

SUMMARY AND CONCLUSIONS

An *in vivo* robot was designed and developed for LESS. The workspace, endpoint speed, and endpoint force capabilities were experimentally measured. In addition, this robot was used to perform a cholecystectomy (gall bladder removal) in a live porcine model. During the surgery, the target position and estimated position of the robot were recorded. The

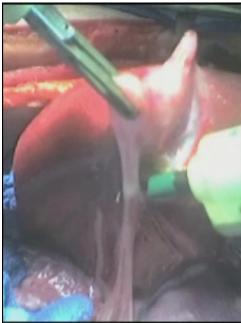


FIGURE 4. PICTURE OF ROBOT ISOLATING THE CYSTIC DUCT WHILE PERFORMING A CHOLECYSTECTOMY

workspace and speeds observed during the surgery were significantly smaller than the capabilities of the robot indicating that the developed robot can follow normal human motions without noticeable motion lag.

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REPORT OF INVENTIONS AND SUBCONTRACTS (Pursuant to "Patent Rights" Contract Clause) (See Instructions on back)										Form Approved OMB No. 9000-0095 Expires Oct 31, 2004				
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MULTI-FUNCTIONAL ROBOT FOR LAPAROENDOSCOPIC SINGLE-SITE SURGERY.

Strabala, K., Wortman, T., Lehman, A., Wood, N., Tiwari, M., Goede, M., Farritor, S., & Oleynikov, D.

Laparo-Endoscopic Single-Site surgery (LESS) is a new alternative to laparoscopic procedures that completely eliminates all but one external incision by using a single specialized port inserted transumbilically, creating a new scar that is hidden in the natural umbilical scar. LESS procedures are difficult to perform without robotic enhancement. The aim of this study is to build a multi-dexterous robot, capable of generating the required forces and speeds to perform specific surgical tasks within the abdomen. Miniature in vivo robots are the future when it comes to overcoming current LESS constraints, such as dexterity, orientation, and visualization. A robotic platform consisting of a miniature in vivo robot and a remote surgeon interface has been designed and built. The basic robot design consists of two arms each connected to a central body. This surgical robot prototype has been used in three animal experiments in a porcine model. In each surgery, multiple procedures were compared to the same procedures performed with SILS laparoscopic approach using conventional tools and techniques. The multi-functional robot developed here was ranked higher than traditional tools by surveyed surgeons using a Likert scale. Miniature surgical robots allow for similar benefits including ease of visualization, better articulation, better triangulation control, and the ability of complex movements that allow the robot to perform dexterous, laparoscopic-like tasks but through a single incision. Future plans involve developing smaller and more agile robots with additional degrees of freedom for more dexterous movement.